



DOCKET NO: C1039.70058US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

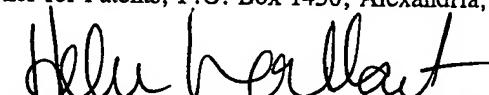
Applicant: Heather L. Davis et al.  
Serial No: 10/023,909  
Confirmation No: 8458  
Filed: 12/18/2001  
For: USE OF NUCLEIC ACIDS CONTAINING UNMETHYLATED CpG DINUCLEOTIDE AS AN ADJUVANT

Examiner: Jeffrey S. Parkin  
Art Unit: 1648

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 10 day of February, 2004.

  
Helen C. Lockhart, Ph.D., Reg. No. 39,248

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office Action, but before the mailing date of either a final action under 37 C.F.R. §1.113 or a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application (copies enclosed):

Docket Number	Serial Number	Filing Date	Inventor(s)
C1037.70013US00	09/776,479	2/2/01	Bratzler et al.
C1037.70016US00	09/009,634	1/20/98	Hutcherson et al.
C1037.70025US00	10/017,995	12/14/01	Bratzler
C1037.70038US01	10/735,592	12/11/03	Krieg et al.
C1037.70041US00	10/613,749	7/3/03	Krieg
C1037.70042US00	10/613,524	7/3/03	Krieg
C1037.70043US00	10/613,739	7/3/03	Krieg
C1037.70044US00	10/613,716	7/3/03	Krieg
C1037.70045US00	10/613,228	7/3/03	Krieg
C1037.70046US00	10/445,247	6/5/03	Krieg
C1037.70048US00	10/644,052	8/19/03	Krieg et al.
C1037.70049US00	10/643,141	8/18/03	Hutcherson et al.
C1037.70051US00	10/666,733	9/19/03	Bratzler et al.
C1037.70052US00	10/668,050	9/22/03	Bratzler et al.
C1039.70021US01	10/719,493	11/21/03	Krieg et al.
C1039.70048US01	TBD	1/30/04	Krieg et al.
C1039.70057US00	09/965,101	9/26/01	Davis et al.
C1039.70060US00	10/112,653	3/29/02	Krieg et al.
C1039.70061US00	10/161,229	6/3/02	Krieg et al.
C1039.70062US00	10/187,489	7/2/02	Krieg et al.
C1039.70063US00	10/224,523	8/19/02	Krieg et al.
C1039.70065US00	10/272,502	10/15/02	Krieg et al.

Docket Number	Serial Number	Filing Date	Inventor(s)
C1039.70067US00	10/300,247	11/20/02	Davis et al.
C1039.70068US00	10/306,522	11/27/02	Krieg et al.
C1039.70069US00	10/314,578	12/9/02	Krieg et al.
C1039.70070US00	10/382,822	3/6/03	Krieg et al.
C1039.70071US00	10/435,656	5/9/03	Krieg et al
C1039.70072US00	10/434,696	5/9/03	Davis et al.
C1039.70073US00	10/743,625	12/22/03	Krieg et al.
C1039.70075US00	10/613,916	7/3/03	Krieg et al
C1039.70077US00	10/619,279	7/14/03	Krieg
C1039.70078US00	10/627,331	7/25/03	Krieg et al.
C1039.70079US00	10/627,413	7/25/03	Krieg et al.
C1039.70082US00	10/631,676	7/30/03	Krieg et al.
C1039.70083US00	10/690,495	10/21/03	Krieg
C1039.70083US01	TBD	1/30/04	Krieg et al.
C1039.70084US00	10/649,584	8/25/03	Krieg et al.
C1041.70016US00	09/954,987	9/17/01	Bauer et al.
C1041.70019US00	10/140,013	5/6/02	Schetter et al.
C1041.70029US00	10/212,133	8/1/02	Lipford et al.
C1041.70031US00	10/265,072	10/5/02	Lipford
C1041.70035US00	10/373,381	2/24/03	Wagner et al.
C1041.70037US00	10/407,952	4/4/03	Lipford et al.
C1041.70040US00	10/666,844	9/19/03	Lipford et al.

The following are remarks concerning the other information cited:

Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;

3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Heather L. Davis et al., *Applicant*

By: Helen C. Lockhart  
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Docket No. C1039.70058US00

Date: February 6, 2004

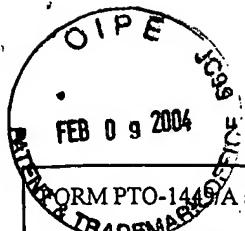
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FORM PTO-149/A and B (Modified)			APPLICATION NO.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00
INFORMATION DISCLOSURE STATEMENT BY APPLICANT			FILING DATE: 12/18/2001	CONFIRMATION NO.: 8458
			APPLICANT: Heather L. Davis et al.	
Sheet	1	of	3	GROUP ART UNIT: 1648 EXAMINER: Jeffrey S. Parkin

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	6,194,388	B1	Krieg et al.	02-27-2001
	A2	6,207,646	B1	Krieg et al.	03-27-2001
	A3	6,214,806	B1	Krieg et al.	04-10-2001
	A4	6,218,371	B1	Krieg et al.	04-17-2001
	A5	6,225,292	B1	Raz et al.	05-01-2001
	A6	6,239,116	B1	Krieg et al.	05-29-2001
	A7	6,339,068		Krieg et al.	01/15/2002
	A8	6,406,705	B1	Davis et al.	06-18-2002
	A9	6,429,199	B1	Krieg et al.	08-06-2002
	A10	6,498,148	B1	Raz	12/24/2002
	A11	6,514,948	B1	Raz, et atl	02/04/2003
	A12	6,534,062	B2	Krieg, et al.	03/18/2003
	A13	6,552,006	B2	Raz et al.	04/22/2003
	A14	6,562,798	B1	Schwartz	05/13/2003
	A15	6,589,940	B1	Raz et al.	07/08/2003
	A16	6,610,661	B1	Carson et al.	08/26/2003
	A17	6,653,292	B1	Krieg et al.	11/25/2003
	A18	US 2001/0046967		Van Nest	11/29/2001
	A19	US 2002/0028784		Van Nest	03/11/2002
	A20	US 2002/0042387		Raz et al.	04/11/2002
	A21	US 2002/0055477	A1	Nest et al	05/09/2002
	A22	US 2002/0086839		Raz et al.	07/04/2002
	A23	US 2002/0098199	A1	Van Nest et al.	07/25/2002
	A24	US 2002/0107212	A1	Van Nest et al.	08/08/2002
	A25	US 2002/0142978	A1	Raz et al.	10/03/2002
	A26	US 2002/0156033	A1	Bratzler et al.	10/24/2002
	A27	US 2003/0022852		Van Nest et al.	1/30/2003
	A28	US 2003/0049266	A1	Fearon et al.	03/13/2003
	A29	US 2003/0050263	A1	Krieg et al.	03/13/2003
	A30	US 2003/0059773		Van Nest et al.	01/30/2003
	A31	US 2003/0064064		Dina	04/03/2003
	A32	US 2003/0078223	A1	Raz et al.	04/24/2003
	A33	US 2003/0092663	A1	Raz	05/15/2003
	A34	US 2003/0109469	A1	Carson et al	06/12/2003
	A35	US 2003/0119773	A1	Raz et al.	06/26/2003
	A36	US 2003/0125284		Raz et al.	07/03/2003



FORM PTO-146 A and B (Modified)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Sheet 2 of 3

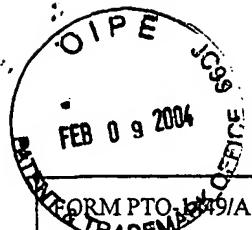
APPLICATION NO.: 10/023,909	ATTY. DOCKET NO.: C1039.70058US00
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APPLICANT: Heather L. Davis et al.	
GROUP ART UNIT: 1648	EXAMINER: Jeffrey S. Parkin

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A37	US 2003/0129251	A1	Van Nest et al.	07/10/2003
	A38	US 2003/0130217		Raz et al.	07/10/2003
	A39	US 2003/0133988	A1	Fearon et al.	07/17/2003
	A40	US 2003/0143213	A1	Raz et al.	07/37/2003
	A41	US 2003/0147870	A1	Raz et al.	08/07/2003
	A42	US 2003/0175731	A1	Fearon et al.	09/18/2003
	A43	US 2003/0176373		Raz et al.	09/18/2003
	A44	US 2003/0186921	A1	Carson et al.	10/02/2003
	A45	US 2003/0199466	A1	Fearon et al.	10/23/2003
	A46	US 2003/0203891		Goebel et al.	10/30/2003
	A47	US 2003/0212028	A1	Raz et al.	11/13/2003
	A48	US 2003/0216340	A1	Van Nest et al.	11/20/2003
	A49	US 2003/0232780		Carson et al.	12/18/2003
	A50	US 2004/0006034		Raz et al.	01/08/2004
	A51	US 2004/0009942		Van Nest et al.	01/15/2004

**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B1	WO	99/11275	A2	Regents of the University of CA	03/11/1999	
	B2	WO	99/62923	A2	Dynavax Tech. Corp	12/09/1999	
	B3	WO	00/20039	A1	Regents of the University of CA	04/13/2000	
	B4	WO	00/62787	A1	Regents of the University of CA	10/26/2000	
	B5	WO	98/55609	A1	Regents of the University of CA	10/12/1998	
	B6	WO	00/21556	A1	Dynavax Tech. Corp	04/20/2000	
	B7	WO	01/02007	A1	Regents of the University of CA	01/11/2001	
	B8	WO	01/12223	A2	Dynavax Tech. Corp	02/01/2001	
	B9	WO	01/55341	A2	Regents of the University of CA	08/02/2001	
	B10	WO	01/68077	A2	Dynavax Tech. Corp	09/20/2001	
	B11	WO	01/68078	A2	Dynavax Tech. Corp	09/20/2001	
	B12	WO	01/68103	A2	Dynavax Tech. Corp	09/20/2001	
	B13	WO	01/68116	A2	Dynavax Tech. Corp	09/20/2001	
	B14	WO	01/68117	A2	Dynavax Tech. Corp	09/20/2001	



FORM PTO-149/A and B (Modified)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

Sheet 3 of 3

APPLICATION NO.:	10/023,909	ATTY. DOCKET NO.:	C1039.70058US00
FILING DATE:	12/18/2001	CONFIRMATION NO.:	8458
APPLICANT:	Heather L. Davis et al.		
GROUP ART UNIT:	1648	EXAMINER:	Jeffrey S. Parkin

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	Elkins, K. L., Rhinehart-Jones, T. R., et al., "Bacterial DNA containing CpG motifs stimulates lymphocyte-dependent protection of mice against lethal infection with intracellular bacteria." <i>J Immunol</i> 162:2291-2298, 1999.	
	C2	Freitag, B. L et al., "CpG oligodeoxynucleotides and interleukin-12 improve the efficacy of <i>Mycobacterium bovis</i> BCG vaccination in mice challenged with <i>M. tuberculosis</i> ." <i>Infect Immun</i> 68:2948-2953, 2000.	
	C3	Hayashi, T. et al., "Enhancement of innate immunity against <i>Mycobacterium avium</i> infection by immunostimulatory DNA is mediated by indoleamine 2,3-dioxygenase." <i>Infect Immun</i> 69:6156-6164, 2001.	
	C4	Juffermans, N. P. et al., "CpG oligodeoxynucleotides enhance host defense during murine tuberculosis." <i>Infect Immun</i> 70:147-152, 2002.	
	C5	Klinman, D. M. et al., "Repeated administration of synthetic oligodeoxynucleotides expressing CpG motifs provides long-term protection against bacterial infection. <i>Infect Immun</i> 67:5658-5663, 1999"	
	C6	Klinman, D. M., et al. Activation of the innate immune system by CpG oligodeoxynucleotides: immunoprotective activity and safety. <i>Springer Semin Immunopathol</i> 22:173-183, 2000	
	C7	Krieg, A. M., et al., "CpG motifs in bacterial DNA and their immune effect." <i>Annu Rev Immunol</i> 20:709-760, 2002.	
	C8	Lipford, G. B. et al. "Immunostimulatory DNA: sequence-dependent production of potentially harmful or useful cytokines." <i>Eur J Immunol</i> 27:3420-3426, 1997.	
	C9	Sedegah, M. et al. "Interleukin 12 induction of interferon g-dependent protection against malaria." <i>Proc Natl Acad Sci USA</i> 91:10700-10702, 1994.	
	C10	Sethi, S. et al. "Postexposure prophylaxis against prion disease with a stimulator of innate immunity." <i>Lancet</i> 360:229-230, 2002.	
	C11	Stacey, K. J et al. "Immunostimulatory DNA as an adjuvant in vaccination against <i>Leishmania major</i> ." <i>Infect Immun</i> 67:3719-3726, 1999	
	C12	Walker, P. S. et al. "Immunostimulatory oligodeoxynucleotides promote protective immunity and provide systemic therapy for leishmaniasis via IL-12- and IFN-g-dependent mechanisms." <i>Proc Natl Acad Sci USA</i> 96:6970-6975, 1999.	
	C13	Zimmermann, S. et al., "CpG oligodeoxynucleotides trigger protective and curative Th1 responses in lethal murine leishmaniasis." <i>J Immunol</i> 160:3627-3630, 1998.	

EXAMINER

DATE CONSIDERED

#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]



1648

ATTORNEY'S DOCKET NO: C1039.70058US00

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Heather L. Davis et al.  
Serial No: 10/023,909  
Confirmation No.: 8458  
Filed: December 18, 2001  
For: USE OF NUCLEIC ACIDS CONTAINING UNMETHYLATED CPG  
DINUCL EOTIDE AS AN ADJUVANT  
Examiner: Jeffrey S. Parkin  
Art Unit: 1648

## CERTIFICATE OF MAILING UNDER 37 C.F.R. 1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on February 6, 2004.

Helen C. Lockhart

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

TRANSMITTAL

Sir:

Transmitted herewith is/are the following document(s):

- Supplemental Information Disclosure Statement;
- PTO Form 1449 (copies of references cited);
- Check in the amount of \$180.00; and
- Return Receipt Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check in the amount of \$180.00 is enclosed. If the fee is insufficient, please charge the balance to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully Submitted,

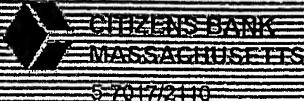
Helen C. Lockhart; Reg. No. 39,248  
Wolf, Greenfield & Sacks, P.C.  
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Docket No. C1039.70058US00  
Date: February 6, 2004  
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Wolf, Greenfield & Sacks, P.C.

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Boston, MA 02210



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February 04, 2004

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Lorraine O'Brien  
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Serial No. 10023,909 File No. C1039.70058US00 By: HCL  
Title: USE OF NUCLEIC ACIDS CONTAINING UNMETHYLATED  
Application of DAVIS ET AL WGS Date: NDD

The U.S. PTO Mail Room acknowledges receipt of the following on the date stamped hereon:

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<input type="checkbox"/> Patent Application [ ] Non-provisional [ ] Provisional Incl. _____ pages, ( _____ pgs) Specification, ( _____ pgs) Abstract, ( _____ pgs) Claims ( _____ # claims)	<input checked="" type="checkbox"/> References Cited Priority Document(s) # _____ Copy of Notice to File Missing Parts
<input type="checkbox"/> Design Patent Application Declaration(s) _____	<input type="checkbox"/> Amendment/Response Petition for Ext. of Time (x2)
<input type="checkbox"/> Drawings _____ Sheet(s) (FIGS. _____) [ ] Formal [ ] Informal	<input type="checkbox"/> Issue Fee Transmittal Assignment and Coversheet
<input type="checkbox"/> Utility Patent Application Transmittal Fee calculation sheet (x2)	<input type="checkbox"/> Notice of Appeal Brief (x3)
<input type="checkbox"/> CPA Transmittal Verified Statement claiming small entity status Request for Approval and Entry of Formal Drawings	<input type="checkbox"/> Check for \$ _____ Check # _____ <input checked="" type="checkbox"/> Transmittal Letter (x2) <input type="checkbox"/> Cert. of Mailing under 37 CFR 1.8(a)
<input type="checkbox"/> Other 2 BOXES OF REFERENCES	

DATE MAILED FEBRUARY 6, 2004